IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PFIZER INC., PHARMACIA CORP., PHARMACIA & UPJOHN INC., PHARMACIA & UPJOHN COMPANY, G.D. SEARLE & CO., G.D. SEARLE LLC, SEARLE LLC (DELAWARE) and SEARLE LLC (NEVADA) Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	)	**CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY** Civil Action No: 04-754 (JCL)

EXPERT REPORT OF DR. HENRY G. GRABOWSKI

I submit this report pursuant to Fed. R. Civ. P. 26 to set forth the opinions I have formed and may offer at trial of this action.

I. Background

Education and Experience

1. I am currently a Professor of Economics and the Director of the Program in Pharmaceuticals and Health Economics at Duke University.

2. I received a B.S. in Engineering Physics from Lehigh University in 1962, and an M.A. and Ph.D in Economics from Princeton University in 1964 and 1967, respectively.

3. From 1967-1971, I was an Assistant Professor in the Economics Department at Yale University. From 1971-1972, I was employed as a Research Associate for the National Bureau of Economic Research. I was an Associate Professor in the Duke University

Economics Department, from 1972-1976, and I became a Professor in 1976, a position I currently hold.

4. I have studied the economics of pharmaceuticals over much of my career. My academic and research specialties concern the Pharmaceutical Industry – Health Economics, Economics of Innovation, and Government Regulation of Business and Industrial Organizations. I have published at least 80 articles and several books on the pharmaceutical industry.

5. Under a series of grants from the National Science Foundation, I examined the economics of pharmaceutical R&D and the effect of various government policy actions on drug innovation. I have testified several times before Congressional committees in the United States on pharmaceutical industry issues. For example, since 1994, I have testified before Congress on issues involving the Clinton Administration's health reform legislation, effective patent life and generic competition in pharmaceuticals, and the federal government's policy toward pediatric vaccines.

6. I have been an advisor and consultant to the National Academy of Sciences, the Institute of Medicine, the Federal Trade Commission, the General Accounting Office and the Office of Technology Assessment. I have also held visiting scholar appointments at the International Institute of Management in Berlin, Germany, the Health Care Financing Administration in Washington, D.C., the Office of Health Economics in London and the Centre for Medicines Research in London. I have been a consultant to most of the major firms in the pharmaceutical industry. Until its acquisition by Gilead Sciences, Inc. in 2003, I served on the Board of Directors of Triangle Pharmaceuticals, Inc., a development stage company which has a number of products in clinical testing.

7. I have significant experience in the economics of competition in the pharmaceutical industry and the market effects of drug product introductions.

8. A copy of my Curriculum Vitae, containing a list of my publications is attached as Exhibit A.

Compensation

9. I am being compensated for my time as an expert witness at the rate of $625 per hour plus reasonable expenses. My compensation is unaffected by the outcome of this litigation.

Prior Testimony

10. In the past four years, I have testified as an expert in the following proceedings:

a. Testimony, Arbitration, *Amgen Inc. v. Ortho Pharmaceutical Corp.*, Chicago, Illinois, May 2002.

b. Testimony, Arbitration, *NeoPharm, Inc. v. Pharmacia & Upjohn Co.*, Washington, D.C., December 2003.

c. Deposition, *New River Pharms v. DSM Pharms,* U.S. District Court for the Eastern District of Tennessee, March 2004.

d. Deposition, *Sanofi-Synthelabo et al. v. Apotex, Inc.*, U.S. District Court for the Southern District of New York, November 2004.

e. Deposition, *In re Bristol-Myers Squibb Securities Litigation*, Civil Action No. 00-1990 (SRC), U.S. District Court for the District of New Jersey, January 2005.

f. Deposition, *Wyeth v. Teva Pharmaceuticals,* Civil Action No. 03-1293 (KSH), U.S. District Court for the District of New Jersey, June 2005.

II. Materials Considered

11. In forming my opinions and preparing this report, I have reviewed and relied upon the materials cited and listed in Exhibit B, attached to this report, and my many years of study of economics and the pharmaceutical industry. This work is reflected in my publication list.

III. Subject Matter About Which I Expect to Testify

12. I presently plan to testify and give opinions concerning the commercial success and licensing of Celebrex®. Based on my analysis below, it is my opinion that Celebrex® has been commercially successful.

13. I may address other matters in response to reports or other evidence offered by Teva. I reserve the right to supplement my report with additional IMS data for 2006. I reserve the right to supplement or amend my opinions in response to opinions expressed by defendant's experts, or in light of any additional evidence, testimony, discovery or other information relating to the aforementioned issues that may be provided to me after the date of this report. In addition, I expect that I may be asked to consider and testify about issues that may be raised by defendant's experts in their reports or at trial.

IV. The NSAID Market (Non-Selective NSAIDs and COX-2 Selective NSAIDs)

14. I understand that non-steroidal anti-inflammatory drugs ("NSAIDs") have been used for decades to treat inflammatory disorders such as arthritis and to ease pain. *See, e.g.,* Brooke, "Cox-2 Inhibitors: Big Market; Big Battle; Big Issues," *Morgan Stanley Dean Witter* (1998), p. 5; Chan, "Celecoxib Versus Diclofenac and Omeprazole in Reducing the Risk of Recurrent Ulcer Bleeding in Patients with Arthritis," *The New England Journal of Medicine*,

347, no. 26 (2002), pp. 2104-2110, 2104. I use the term NSAID to mean any non-steroidal anti-inflammatory drug.

15. Despite their widespread use, I understand that NSAIDs have been associated with certain undesirable side effects. Most notably, NSAIDs can damage the gastrointestinal lining, resulting in problems ranging from discomfort to ulcers and, in the worst cases, blood loss and even death. *See, e.g.,* Brooke, p. 2; Chan, p. 2104. I further understand that a reason for these side effects is believed to be due to the fact that "conventional, nonselective NSAIDs" inhibited both the enzyme responsible for the anti-inflammatory response (commonly referred to as "cylcooxygenase 2" or "COX-2") and the enzyme responsible for protecting the gastrointestinal tract (commonly referred to as "cyclooxygenase 1" or "COX-1"). *See, e.g.,* Chan, p. 2104. For purposes of this report, I will refer to these "conventional" NSAIDs (*id.*) as Non-Selective NSAIDs. *Id.*; *see also* PFC01547622-25 (FDA website).

16. I understand that pharmaceutical companies searched for safer NSAIDs, and one effort was the development of a new class of drugs that selectively inhibit the COX-2 enzyme more than the COX-1 enzyme. *See, e.g.,* Brooke, p. 2; Chan, p. 2104. Drugs in this class of NSAIDs are commonly referred to as COX-2 Selective NSAIDS. *See, e.g.,* PFC01547622-25 (FDA website).

17. The COX-2 Selective NSAID market at one time comprised the first-in-class Celebrex® (Reuters, "Monsanto's 2d-Quarter Profit Beats Analysts' Expectations," *New York Times*, July 28, 1999), Vioxx®, and Bextra®. *See, e.g.,* PFC01547622-25; PFC01534663. Celebrex®, which I understand was developed by G.D. Searle & Co. ("Searle") and co-promoted with Pfizer (PFC01534897-937), was launched in January 1999 (1999 IMS data; PFC01534472-73), and is the only COX-2 Selective NSAID on the market today. (2005 IMS data). I understand

Vioxx® was developed and marketed by Merck and launched in May, 1999. (1999 IMS data; PFC01534472-73). I understand that Vioxx® was voluntarily removed from the market on September 30, 2004. (2004-2005 IMS data; PFC01535137). Bextra® was developed by Searle and was also co-promoted with Pfizer. (1999-2005 IMS data; PFC01534633). I understand Bextra® was launched in April, 2002 (2002 IMS data; PFC01534663) and was voluntarily removed from the market by Pfizer in April, 2005. (2005 IMS data; PFC01547622 (FDA website)).

18. Throughout this report, I will use the following market definitions:

a. "NSAID market" means the U.S. prescription drug market for all NSAIDs (Non-Selective NSAIDs and COX-2 Selective NSAIDs). *See* PFC01547622-25 (FDA website).

b. "COX-2 Selective NSAID market" means the U.S. prescription drug market comprising Celebrex®, Vioxx® and Bextra®. *See* PFC01547622-25 (FDA website).

c. "Non-Selective NSAID market" means the U.S. prescription drug market comprising all Non-Selective NSAIDS. *See* PFC01547622-25 (FDA website).

V. Commercial Success Analysis

19. I understand that commercial success of a product can be used as a consideration in demonstrating the non-obviousness of the underlying patented invention. In evaluating commercial success of Celebrex® in the U.S. prescription drug market, I considered a number of factors, including U.S. sales and prescription volume, NSAID market expansion and penetration, U.S. market share growth and the present value of U.S. sales of Celebrex® and other NSAIDs discounted back to the year of launch, to support a finding of commercial success.

20. Throughout my report, I rely on data from IMS, a third-party market research and consulting company that compiles pharmaceutical data regarding sales, prescription volume and prescription share, and makes the data available to pharmaceutical companies and other organizations by subscription. IMS is recognized as the industry standard and is the most frequently used source of data in the pharmaceutical industry. I have worked with IMS data in my research and consulting work for more than two decades.

United States Sales and Prescription Volume of Celebrex®

21. An initial indication of the commercial success of a product is its sales, measured in terms of total dollars and total number of prescriptions. Celebrex® proved to be the most successful drug introduction ever, with more than seven million prescriptions in the first six months. *See* Reuters, July 28, 1999. Celebrex® achieved $1.4 billion in U.S. sales in 1999. *See, e.g.*, Figure 1). From 1999, its first year on the market, through 2004, Celebrex® was among the top twelve drugs in terms of U.S. sales, and was within the top ten from 2000 through 2003. (PFC01534442; PFC01534499; PFC01534554; PFC01534607; PFC01535188; PFC01535068).

22. Since its launch in 1999, Celebrex® has consistently led the COX-2 Selective NSAID market in U.S. sales and U.S. prescription volume – consistently exceeding both Vioxx® and Bextra® in those categories. *See* Figure 2; Figure 4. Today, as the only COX-2 Selective NSAID remaining on the market (*see* ¶17, *supra*), Celebrex® accounts for all U.S. sales and prescriptions in the COX-2 Selective NSAID market.

23. Celebrex®'s U.S. sales in 1999 were also more than three times the U.S. sales of any Non-Selective NSAID on the market. *See* Figure 1. As illustrated in Figure 1, since its launch in 1999, the U.S. sales of Celebrex® have significantly exceeded the sales of the

leading Non-Selective NSAIDs.[1] *See* Figure 1. In 2005, Celebrex® accounted for roughly 44% of all U.S. sales in the NSAID market.

24. Similarly, Celebrex® also became the market leader in the NSAID market (2000) in total number of U.S. prescriptions where it competes with less expensive generic NSAIDs in addition to other branded NSAIDs, a position it held until 2005. *See* Figure 3. With 14.3 million prescriptions in 2005, Celebrex® was second only to Ibuprofen in total number of U.S. prescriptions of all drugs in the NSAID market. *Id.*

Market Expansion and Penetration

25. Another hallmark of a commercially successful product is that it substantially expands the size of its market. Celebrex® has not only substantially expanded the NSAID market, but, as the first COX-2 Selective NSAID (*see* Reuters, July 28, 1999), Celebrex® has established and led the COX-2 Selective NSAID market.

26. By the time Celebrex® was launched in January, 1999, the NSAID market contained several branded and unbranded drugs. *See* 1999-2005 IMS data. In the years preceeding the launch of Celebrex®, the total U.S sales and total U.S. prescriptions of drugs in the NSAID market had been stagnant. *See* Figures 5 & 6. In 1998, the U.S sales and total U.S. prescriptions for the NSAID market were $2.24 billion and 79.5 million, respectively. *Id.*

27. As illustrated in Figures 5 and 6, the NSAID market experienced a significant expansion in 1999 with the launch of Celebrex® followed by Vioxx®. In 1999, total U.S. sales in the NSAID market rose 62% to $3.65 billion and total U.S prescriptions rose 21% to 96.1 million. *Id.* This expansion in 1999 was due primarily to the introduction of COX-2

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[1] "Leading" Non-Selective NSAIDs means those Non-Selective NSAIDs that account for the largest percentage of U.S. sales and prescriptions since 1998.

Selective NSAIDs – largely the introduction of Celebrex® ($1.42 billion in U.S. sales and 17.5 million U.S. prescriptions). *Id.*

28. By 2004, the NSAID market had expanded to $6.5 billion in U. S. sales and 113 million U.S. prescriptions, with Celebrex® and the other COX-2 Selective NSAIDs accounting for 83% (Celebrex®, 43%) of U.S. sales in the NSAID market and 45% (Celebrex, 21.2%) of U.S. prescriptions in the NSAID market. *See* Figures 5 & 6.

29. Even though U.S. sales in the NSAID market declined in 2005 to approximately $3.6 billion in U.S. sales and 91.6 million total U.S. prescriptions, both numbers still exceeded the U.S. sales and prescription volume attained by the NSAID market in 1998 (before the launch of Celebrex® and the other COX-2 Selective NSAIDs).

30. Further evidence of Celebrex®'s commercial success is the rapidity with which it was adopted by the marketplace. Celebrex® sales (both in terms of U.S. dollars and number of U.S. prescriptions) grew at a rapid rate from launch. *See* Figures 1-4. It was reported that, within 6 months, Celebrex® proved to be the most successful product launch ever. *See* Reuters, July 28, 1999.

Market Share Growth

31. It is important from an economic perspective to look at the growth of share within the NSAID market. A commercially successful product will achieve significant market share within its therapeutic category.

32. Celebrex® has consistently led the COX-2 Selective NSAID market in percent market share. Due to the withdrawal of Vioxx® (in September 2004), Celebrex® comprised 89% of the COX-2 Selective NSAID market share in 2005. With the withdrawal of Bextra® (in April 2005), Celebrex® now comprises 100% of the COX-2 Selective NSAID market

share. *See* Figure 8.

33. Celebrex® achieved an 18.3% share of the NSAID market in its first year (1999) and became the market leader in its second year after launch. *See* Figure 7. Celebrex® has held market share in the range of roughly 15-24% of total U.S. prescriptions in the NSAID market. *Id.* Furthermore, the group of Non-Selective NSAIDs experienced declining trends in both U.S. prescriptions and U.S. market share after Celebrex® and the other COX-2 Selective NSAIDs were introduced. *See* Figures 3 & 7.

34. As detailed in Figure 7, within the first three years of launch, 1999 through 2001, the COX-2 Selective NSAIDs Celebrex® and Vioxx® captured U.S. prescription market share from each of the leading Non-Selective NSAIDs (Relafen®, Daypro®, Arthrotec®, Diclofenac Sodium, Ibuprofen, Naproxen, and Lodine XL®)[2]. *Id.* In each of the three years, the market share of the leading Non-Selective NSAIDs decreased, while the market share of Celebrex® and Vioxx® increased. *Id.*

35. From 2002-2004, market shares of most leading Non-Selective NSAIDs continued to decline, with only Diclofenac Sodium and Naproxen experiencing small market share gains. *See* Figure 7. In 2005, Celebrex® still held 15.6% market share of the NSAID market, second only to Ibuprofen. *Id.*

Celebrex® Present Value

36. A further economic indication demonstrating Celebrex®'s commercial success is the present value of the drug measured at the point of market launch. The present value allows one to summarize the economic value of an entire revenue stream. The sales

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[2] Mobic® is not included because it was not launched until May, 2000 – after the launch of Celebrex® and Vioxx®.

incurred in future periods are discounted back to the date of market launch using an appropriate cost of capital.

37. As set forth in Figure 9, I have calculated the present value of the NSAIDs launched from 1999-2005 (COX-2 Selective NSAIDs, Celebrex®, Vioxx®, Bextra®; and the Non-Selective NSAID, Mobic®), cumulatively each year from launch. I have discounted each drug based on its year of launch. I have used a 10% cost of capital to calculate the discounted revenue which is within the accepted range of cost of capital utilized for the pharmaceutical industry. As detailed in Figure 9, Celebrex® has been significantly more valuable, in every time horizon, in every year since launch compared to Vioxx®, Bextra®, and Mobic®. From an economist's point of view, if a prospective buyer was offered each of these drugs from launch, based on the economic value of future revenue, Celebrex® would be the overwhelming choice. Celebrex®'s cumulative present value of $11.3 billion (discounted back to the year of launch), taking into account just the first 7 years of its U.S. sales, puts it in a category of the highest value drugs.

VI. Licensing

38. I understand that licensing can also be used as a consideration for evaluating non-obviousness.

39. In February 1998, Searle and Pfizer entered into two co-promotion agreements – one covering the United States and a separate agreement covering the rest of the world. [redacted]

40. [redacted]

[redacted]

As discussed above, U.S. sales of Celebrex® more than tripled the goals set for these years. *See* Figure 1. U.S. sales of Celebrex® also exceeded analysts' expectations. In 1999, Morgan Stanley projected that the COX-2 Selective NSAID market in 2004 would reach $2.8 billion in U.S. sales. Brooke, p. 10. As shown in Figure 1, by 2004 Celebrex® alone, with roughly $2.8 billion in U.S. sales, met this projection.

41. [redacted]

42. Further evidence of non-obviousness of the inventions claimed by the patents-in-suit is the fact that Pfizer licensed another compound, deracoxib (marketed under the tradename Deramaxx®) to Novartis Animal Health, Inc. (PFC01534938-5010). I am informed that deracoxib is covered by the claims of the patents-in-suit. [redacted]

Dated: May 5, 2006

Henry G. Grabowski

Dr. Henry G. Grabowski

EXHIBIT A

VITA

Henry George Grabowski

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Born: September 20, 1940 in Scranton, Pennsylvania
Married, three children

Education:

Lehigh University, B.S., Engineering Physics, 1962
Princeton University, M.A., Economics, 1964
Princeton University, Ph.D., Economics, 1967

Professional Career:

Assistant Professor in Economics Department, Yale University, 1967-1971
Research Associate, National Bureau of Economic Research, 1971-1972
Associate Professor in Economics Department, Duke University, 1972-1976
Professor in Economics Department, Duke University, 1976-
Research Fellow, International Institute of Management, Berlin, Germany, 1976
Visiting Scholar, Health Care Financing Administration, Office of Research, Washington, D.C. 1979-1980
Director, Program in Pharmaceuticals and Health Economics, Duke University, 1983-

Professional Organizations and Board Memberships:

Adjunct Scholar and Advisory Board Member for Health Policy Research,
American Enterprise Institute for Public Policy Research
Board of Scientific Advisors, American Council on Science and Health
Associate Editor, The Quarterly Review of Economics and Finance
Associate Editor, Journal of Research in Pharmaceutical Economics

Major Fields of Interest:

Industrial Organization
Economics of Innovation
Economics
Government Regulation of Business
Pharmaceutical Industry-Health

Publications

Books and Monographs:

Drug Regulation and Innovation: Empirical Evidence and Policy Options, (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1976.

The Impact of Regulation on Industrial Innovation (with John Vernon) (National Academy of Sciences: Washington, D.C.), 1979.

The Regulation of Pharmaceuticals: Balancing the Benefits and Risks (with John Vernon) (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1983.

Health Reform and Pharmaceutical Innovation (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1994.

The Search for New Vaccines: The Effects of the Vaccines for Children Program, (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1997.

Articles:

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October 2003, Columbia University, December 2003.

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"The Hatch-Waxman Act and Drug Innovation," Food and Drug Law Institute Conference, Washington, DC, December 2004.

"Developing Drugs for Developing Countries," American Economic Association Meetings, Philadelphia, PA, January 2005; also International Health Economics Congress, Barcelona, Spain, July 2005.

"Generic Competition in Pharmaceuticals," International Conference on Pharmaceutical Innovation, Taipei, Taiwan, May 2005.

"Impact of Generic Competition on Pharmaceutical Markets," International Health Economics Congress, Barcelona, Spain, July 2005.

Research Grants and Government Projects:

Principal Investigator, National Science Foundation Grant to Yale University, "Collaborative Research on Determinants of Selected Firm Outlays," June 1969 - December 1970. ($9,800.00)

Principal Investigator, National Science Foundation Grant to NBER for research on "The Returns to Firm Investment Outlays, Plant and Equipment and Advertising Outlays," 1972-1974. ($47,900.00)

Principal Investigator, National Science Foundation Grant for Research on "The Effect of Product Quality Regulation on Innovation: The Case of the U.S. Ethical Pharmaceutical Industry," 1975-1978. ($111,700.00)

Consultant, Federal Trade Commission project on "The Effects of Repealing Anti-Substitution Laws on Drug Innovation," 1977-1978.

Study Rapporteur, National Academy of Sciences Committee on Technology and International Economic and Trade Issues, "The Impact of Government Regulation on Innovation," 1978-1979.

Principal Investigator, National Science Foundation Grant to Duke University for "Studies on Drug Substitution, Patent Policy and Innovation," 1979-1982. ($125,979.00)

Advisory Panel Member, Office of Technology Assessment, The Patent System and Its Assessment on New Technological Enterprises, 1982-1983.

Principal Investigator, Environmental Protection Agency Grant to Investigate the Effects of Regulation on Innovation in Pesticides, (with Kip Viscusi of the Fuqua School of Business), 1983-1984.

Member, Committee on Public-Private Sector Relations in Vaccine Innovation," Institute of Medicine, National Academy of Sciences, 1983-1985.

Principal Investigator, General Accounting Office, Research Project on the Effects of Different State Regulations on Automobile Insurance Premiums and Availability, 1984-1985.

Principal Investigator, Duke University, Program in Pharmaceuticals and Health Economics, Project on Cost Containment and Pharmaceutical Innovation, 1985-1991.

Principal Investigator, Duke University, Program in Pharmaceuticals and Health Economics, Project on Returns to Pharmaceutical R&D, 1990-1994.

Principal Investigator, Program in Pharmaceuticals and Health Economics, "Public Policy and Innovation in the Vaccine Industry," 1995-1997.

Principal Investigator, Program in Pharmaceuticals and Health Economics, "New Research on the Costs and Returns to R&D," 1998-2002.

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EXHIBIT B

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The following documents from plaintiffs' production

Bates First	Bates Last
PFC01236926	PFC01236939
PFC01236940	PFC01236950
PFC01239508	PFC01239540
PFC01534430	PFC01534486
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PFC01547622	PFC01547625
PFC01578962	PFC01578972

Bates First	Bates Last
PFC01579924	PFC01579942
PFC01579968	PFC01579973
PFC01582058	PFC01582065

Additional documents which I understand are being Bates numbered and will be identified.

CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of the foregoing Expert Report of Dr. Henry Grabowski to be served by electronic mail on the 5th day of May 2006 on the counsel for the defendant as follows:

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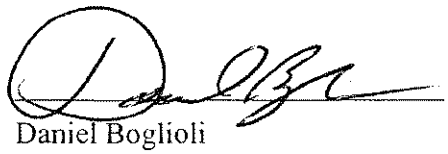

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Education:

Lehigh University, B.S., Engineering Physics, 1962
Princeton University, M.A., Economics, 1964
Princeton University, Ph.D., Economics, 1967

Professional Career:

Assistant Professor in Economics Department, Yale University, 1967-1971
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Associate Professor in Economics Department, Duke University, 1972-1976
Professor in Economics Department, Duke University, 1976-
Research Fellow, International Institute of Management, Berlin, Germany, 1976
Visiting Scholar, Health Care Financing Administration, Office of Research, Washington, D.C. 1979-1980
Director, Program in Pharmaceuticals and Health Economics, Duke University, 1983-

Professional Organizations and Board Memberships:

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Associate Editor, The Quarterly Review of Economics and Finance
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Major Fields of Interest:

Industrial Organization
Economics of Innovation
Economics
Government Regulation of Business
Pharmaceutical Industry-Health

Publications

Books and Monographs:

Drug Regulation and Innovation: Empirical Evidence and Policy Options, (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1976.

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"The Administration's Health Reform Plan--Implications for Pharmaceutical Innovation," testimony before Congressman Waxman's House Subcommittee on Health and the Environment, February 1994.

"Socially Optimal Reimbursement and Utilization Policies for Pharmaceuticals," Hungarian National Social Insurance Administration, Budapest, Hungary, April 1994.

"Pharmaceuticals and Quality of Life: An Economist's Perspective," Forum Engelberg, Engelberg, Switzerland, April 1994.

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"Patents and the Development of New Pharmaceuticals in Pharmaceuticals and Biotechnology Industry," Federal Reserve Bank of Dallas, April 2002.

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"Increasing R&D Incentives for Neglected Diseases," Duke University Law School Conference, April 2003; St. Vincent's College, September 2003; Georgetown University,

October 2003, Columbia University, December 2003.

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"Global Returns on R&D From New Drug Introductions," Keio University, Tokyo, Japan, September 2003.

"R&D Costs and Returns by Therapeutic Category," Southern Economic Association Meetings, San Antonio, Texas, November 2003.

"The Hatch-Waxman Act and Drug Innovation," Food and Drug Law Institute Conference, Washington, DC, December 2004.

"Developing Drugs for Developing Countries," American Economic Association Meetings, Philadelphia, PA, January 2005; also International Health Economics Congress, Barcelona, Spain, July 2005.

"Generic Competition in Pharmaceuticals," International Conference on Pharmaceutical Innovation, Taipei, Taiwan, May 2005.

"Impact of Generic Competition on Pharmaceutical Markets," International Health Economics Congress, Barcelona, Spain, July 2005.

Research Grants and Government Projects:

Principal Investigator, National Science Foundation Grant to Yale University, "Collaborative Research on Determinants of Selected Firm Outlays," June 1969 - December 1970. ($9,800.00)

Principal Investigator, National Science Foundation Grant to NBER for research on "The Returns to Firm Investment Outlays, Plant and Equipment and Advertising Outlays," 1972-1974. ($47,900.00)

Principal Investigator, National Science Foundation Grant for Research on "The Effect of Product Quality Regulation on Innovation: The Case of the U.S. Ethical Pharmaceutical Industry," 1975-1978. ($111,700.00)

Consultant, Federal Trade Commission project on "The Effects of Repealing Anti-Substitution Laws on Drug Innovation," 1977-1978.

Study Rapporteur, National Academy of Sciences Committee on Technology and International Economic and Trade Issues, "The Impact of Government Regulation on Innovation," 1978-1979.

Principal Investigator, National Science Foundation Grant to Duke University for "Studies on Drug Substitution, Patent Policy and Innovation," 1979-1982. ($125,979.00)

Advisory Panel Member, Office of Technology Assessment, The Patent System and Its Assessment on New Technological Enterprises, 1982-1983.

Principal Investigator, Environmental Protection Agency Grant to Investigate the Effects of Regulation on Innovation in Pesticides, (with Kip Viscusi of the Fuqua School of Business), 1983-1984.

Member, Committee on Public-Private Sector Relations in Vaccine Innovation," Institute of Medicine, National Academy of Sciences, 1983-1985.

Principal Investigator, General Accounting Office, Research Project on the Effects of Different State Regulations on Automobile Insurance Premiums and Availability, 1984-1985.

Principal Investigator, Duke University, Program in Pharmaceuticals and Health Economics, Project on Cost Containment and Pharmaceutical Innovation, 1985-1991.

Principal Investigator, Duke University, Program in Pharmaceuticals and Health Economics, Project on Returns to Pharmaceutical R&D, 1990-1994.

Principal Investigator, Program in Pharmaceuticals and Health Economics, "Public Policy and Innovation in the Vaccine Industry," 1995-1997.

Principal Investigator, Program in Pharmaceuticals and Health Economics, "New Research on the Costs and Returns to R&D," 1998-2002.

Principal Investigator, "Increasing R&D Incentives for Neglected Diseases," 2002–2005.

Figure 1: U.S. Sales of COX-2 Selective NSAIDs and Leading Non-Selective NSAIDs

Drugs	1998	1999	2000	2001	2002	2003	2004	2005
Celebrex®		1,418	2,167	2,549	2,586	2,600	2,787	1,598
Bextra®					453	940	1,255	174
Vioxx®		373	1,526	2,049	1,838	1,821	1,351	0
Relafen®/Nabumetone	531	447	343	303	146	103	100	140
Daypro®/Oxaprozin	370	284	169	79	33	20	17	20
Arthrotec®	200	236	157	154	152	155	143	196
Naproxen	300	228	197	122	109	88	81	69
Diclofenac Sodium	260	210	152	87	71	62	68	67
Lodine XL®	146	128	69	21	12	7	3	1
Ibuprofen	69	80	76	64	66	61	61	67
Mobic®			38	157	230	310	505	1,095
All Other	367	242	176	156	154	140	135	173
Total	2,244	3,646	5,071	5,740	5,849	6,305	6,505	3,600

Generic nabumetone and oxaprozin are introduced in 2001.
Vioxx® was launched in May 1999.
Bextra® was launched in January 2002.
Mobic® was launched in May 2000.

*1999-2005 IMS Data, "National Sales Perspectives"; PFC01534472-73

Figure 2: U.S. Sales of COX-2 Selective NSAIDs (Celebrex®, Vioxx® and Bextra®)

Drugs	1998	1999	2000	2001	2002	2003	2004	2005
Celebrex®		1,418	2,167	2,549	2,586	2,600	2,787	1,598
Vioxx®		373	1,526	2,049	1,838	1,821	1,351	0
Bextra®					453	940	1,255	174

Vioxx® was launched in May 1999.
Bextra® was launched in January 2002.

*1999-2005 IMS data, "National Sales Perspectives."

Figure 3: U.S. Prescriptions of COX-2 Selective NSAIDs and Leading Non-Selective NSAIDs

Drugs	1998	1999	2000	2001	2002	2003	2004	2005
Celebrex®		17.5	24.9	27.1	26.0	23.7	23.9	14.3
Bextra®					5.2	10.4	12.8	1.8
Vioxx®		4.8	20.6	25.4	22.0	19.8	13.9	0.0
Relafen®/Nabumetone	8.7	7.1	5.1	4.1	3.5	3.3	3.5	5.1
Daypro®/Oxaprozin	5.7	4.0	2.1	1.4	1.1	1.0	1.0	1.3
Arthrotec®	2.9	3.2	2.0	1.8	1.7	1.6	1.4	1.8
Naproxen	16.2	15.7	14.7	14.0	13.8	13.8	14.6	13.9
Diclofenac Sodium	5.6	4.9	4.0	3.7	3.6	3.7	4.2	5.9
Lodine XL®	2.4	2.0	1.0	0.2	0.1	0.1	0.0	0.0
Ibuprofen	22.6	23.7	22.9	22.8	23.2	23.2	23.3	26.4
Mobic®			0.5	2.3	2.9	3.3	4.6	9.2
All Other	15.5	13.0	11.0	10.2	9.6	9.2	9.5	11.9
Total	79.5	96.1	108.8	112.8	112.8	112.9	112.7	91.5

Generic nabumetone and oxaprozin are introduced in 2001.
Vioxx® was launched in May 1999.
Bextra® was launched in January 2002.
Mobic® was launched in May 2000.

*1999-2005 IMS data, "National Prescription Audit"; PFC01534472-73.

Figure 4: U.S. Prescriptions of COX-2 Selective NSAIDs (Celebrex®, Vioxx® and Bextra®)

Drugs	1998	1999	2000	2001	2002	2003	2004	2005
Celebrex®		17.5	24.9	27.1	26.0	23.7	23.9	14.3
Vioxx®		4.8	20.6	25.4	22.0	19.8	13.9	0.0
Bextra®					5.2	10.4	12.8	1.8

Vioxx® was launched in May 1999.
Bextra® was launched in January 2002.

*1999-2005 IMS data, "National Prescription Audit."

Figure 5: U.S. Sales of NSAIDs Pre and Post Celebrex® Launch

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
All NSAIDS (Non-Selective and COX-2 Selective)				3,646	5,071	5,740	5,849	6,305	6,505	3,600
All Non-Selective NSAIDs & Celebrex®				3,273	3,545	3,691	3,558	3,544	3,899	3,426
All Non-Selective NSAIDs	2,162	1,875	2,244	1,855	1,378	1,142	972	944	1,112	1,828

*1999-2005 IMS data, "National Sales Perspectives"; PFC01534472-73; 1997 & 1998 U.S. Market Performance & Promotion Summary.

Figure 6: Total U.S. Prescriptions of NSAIDs Pre and Post Celebrex® Launch

	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
All NSAIDS (Non-Selective and COX-2 Selective)				96.1	108.8	112.8	112.8	112.9	112.7	91.5
All Non-Selective NSAIDs & Celebrex®				91.3	88.2	87.4	85.6	82.7	86.0	89.7
All Non-Selective NSAIDs	78.3	76.4	79.5	73.8	63.3	60.3	59.6	59.0	62.1	75.4

1999-2005 IMS data, "National Prescription Audit"; PFC01534472-73; 1997 & 1998 U.S. Market Performance & Promotion Summary.

Figure 7: NSAID Market Share From 1999-2005

Drugs	1999	2000	2001	2002	2003	2004	2005
Celebrex®	18.3	22.9	24.0	23.1	20.9	21.2	15.6
Vioxx®	5.0	19.0	22.5	19.5	17.6	12.3	0.0
Bextra®	0	0	0	4.6	9.2	11.4	1.9
Relafen®/Nabumetone	7.4	4.7	3.6	3.1	2.9	3.1	5.6
Daypro®/Oxaprozin	4.1	1.9	1.3	1.0	0.9	0.9	1.4
Arthrotec®	3.4	1.8	1.6	1.5	1.4	1.2	1.9
Naproxen	15.8	13.3	12.2	12.1	12.1	12.9	15.1
Diclofenac Sodium	3.6	3.1	3.0	3.1	3.2	3.7	6.3
Lodine XL®	2.1	0.9	0.2	0.1	0.1	0.0	0.0
Ibuprofen	24.0	20.6	19.9	20.3	20.4	20.6	28.7
Mobic®	0.0	0.5	2.0	2.3	2.9	4.1	10.0
All Others	16.3	11.3	9.7	9.3	8.4	8.6	13.5

Vioxx® was launched in May 1999.
Bextra® was launched in January 2002.
Mobic® was launched in May 2000.

*1999-2005 IMS data, "National Prescription Audit."

Figure 8: COX-2 Selective NSAID Market Share

Drugs	1999	2000	2001	2002	2003	2004	2005
Celebrex®	78%	55%	52%	49%	44%	47%	89%
Vioxx®	22%	45%	48%	41%	37%	27%	0%
Bextra®				10%	19%	25%	11%

*1999-2005 IMS data, "National Prescription Audit."

Figure 9: Cumulative Present Value of U.S. Sales Discounted Back to the Year of Launch By Year Through 2005 of Four NSAIDs Launched From 1999-2005

Drugs	Cumulative ByYear in Year 1 Dollars						
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Celebrex®	1,352	3,230	5,239	7,091	8,785	10,435	11,295
Vioxx®	736	2,270	3,894	5,162	6,350	6,800	6,800
Bextra®	432	1,247	2,236	2,360			
Mobic®	70	240	432	678	1,158	1,597	

Discount Rate = 10% applied to discount all dollars to present value as of year 1 (launch)

Vioxx® was launched in May 1999. Sales in year 7 include May-December 2005 only.
Bextra® was launched in January 2002.
Mobic® was launched in May 2000. Sales in year 6 include May-December 2005 only.

*1999-2005 IMS data, "National Sales Perspectives."

Figure 1: U.S. Sales of COX-2 Selective NSAIDs and Leading Non-Selective NSAIDS

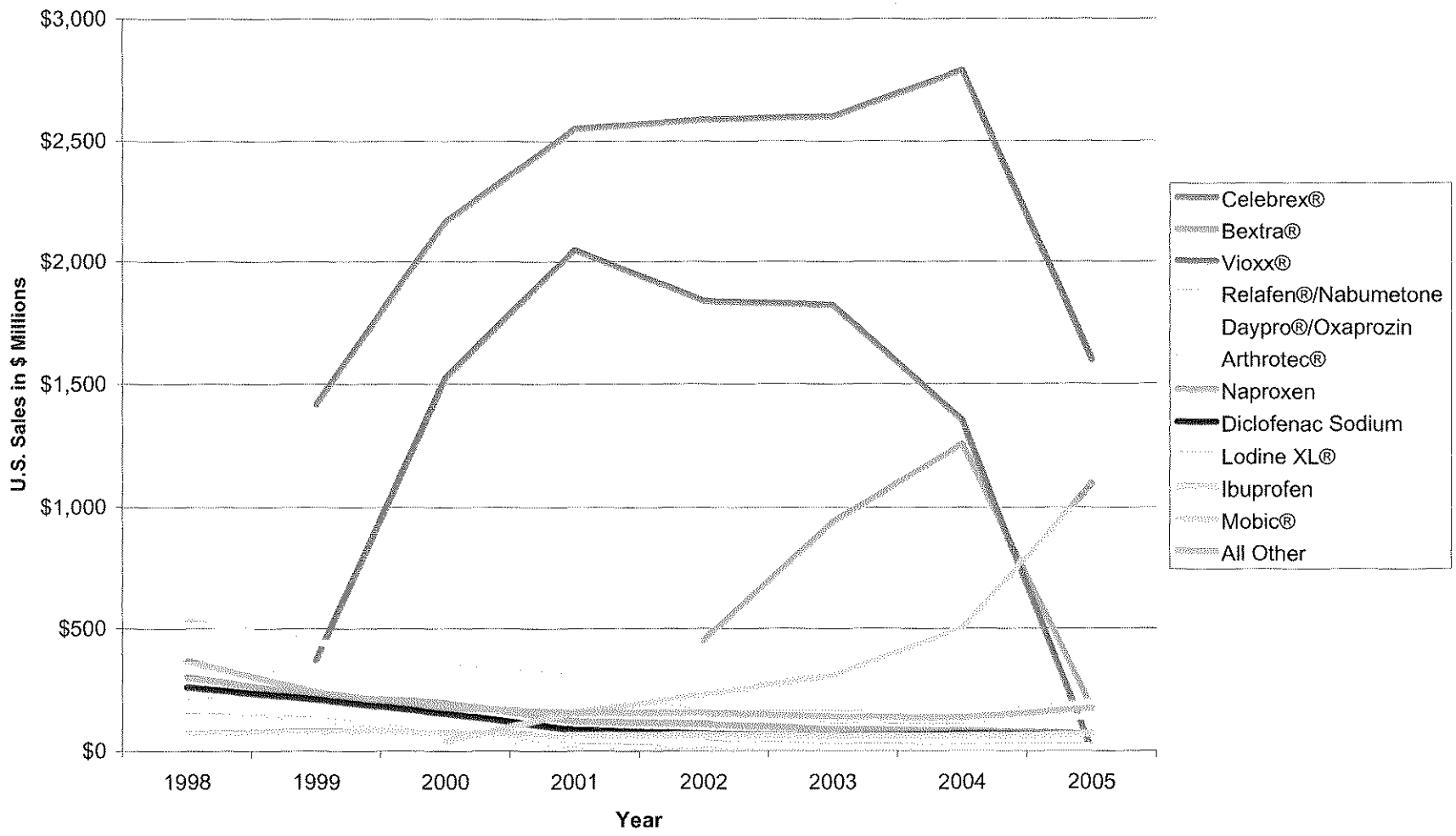

Figure 2: U.S. Sales of COX-2 Selective NSAIDs (Celebrex®, Vioxx® and Bextra®)

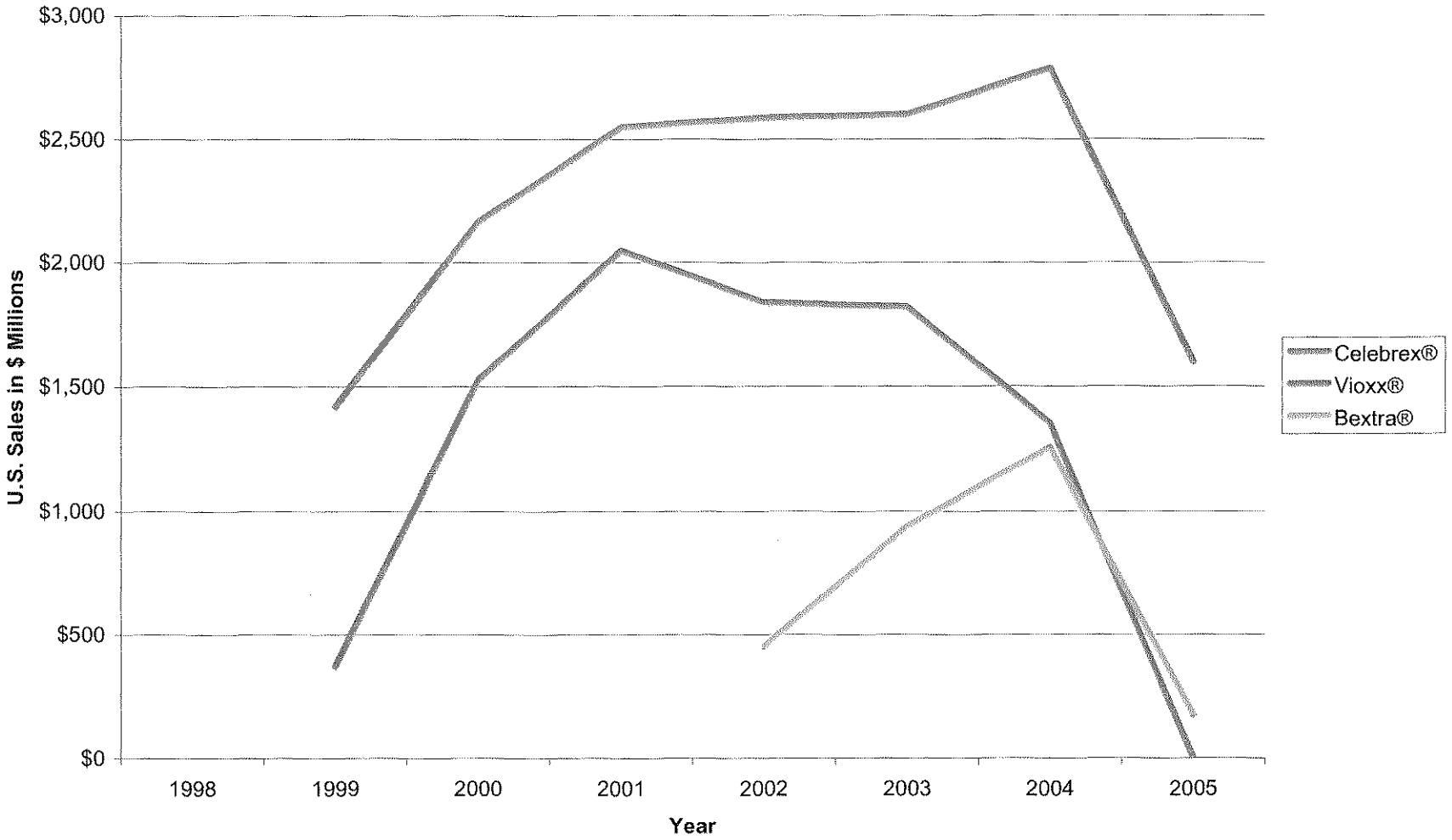

Figure 3: U.S. Prescriptions of COX-2 Selective NSAIDs and Leading Non-Selective NSAIDS

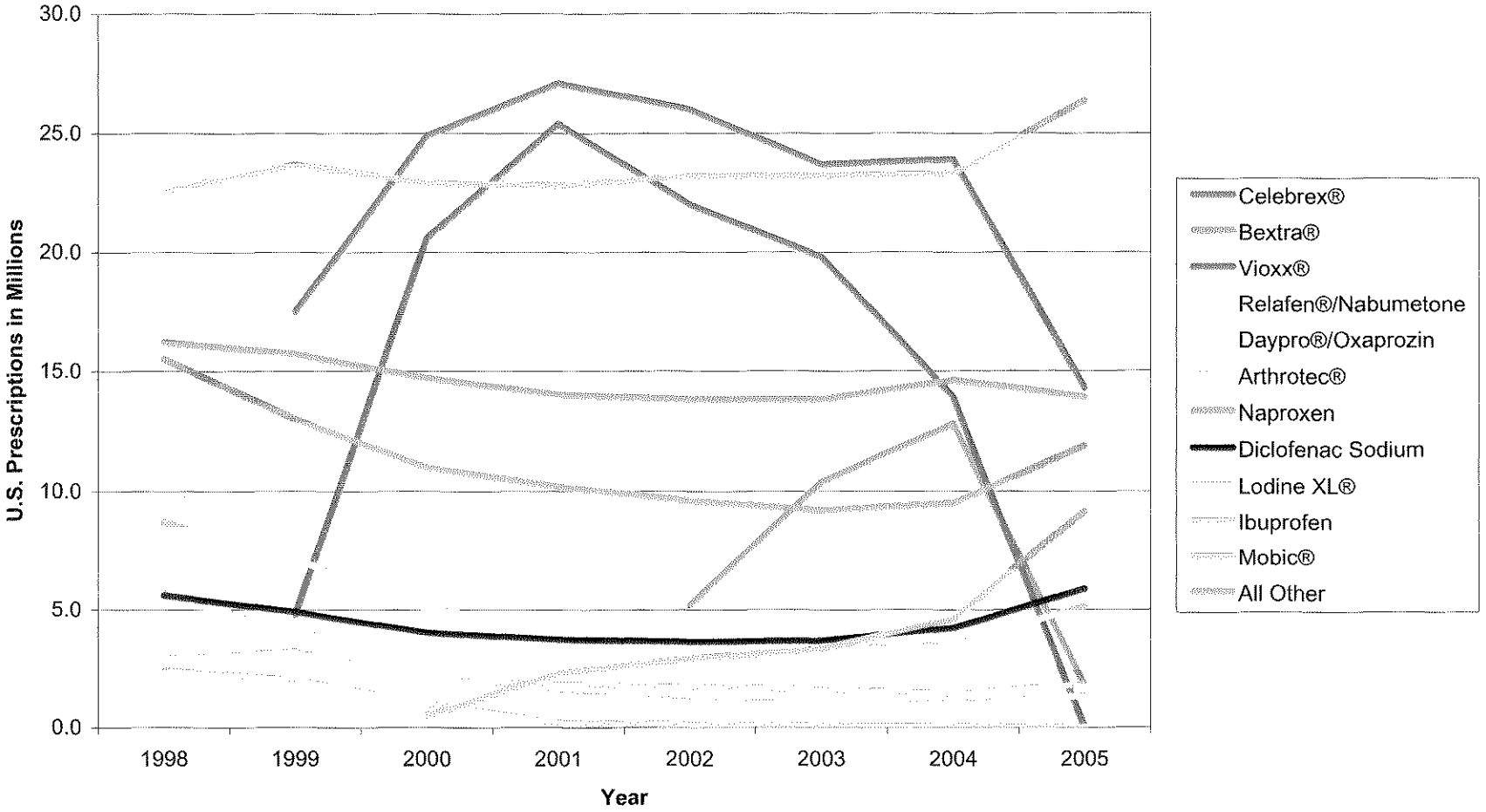

Figure 4: U.S. Prescriptions of COX-2 Selective NSAIDs (Celebrex®, Vioxx® and Bextra®)

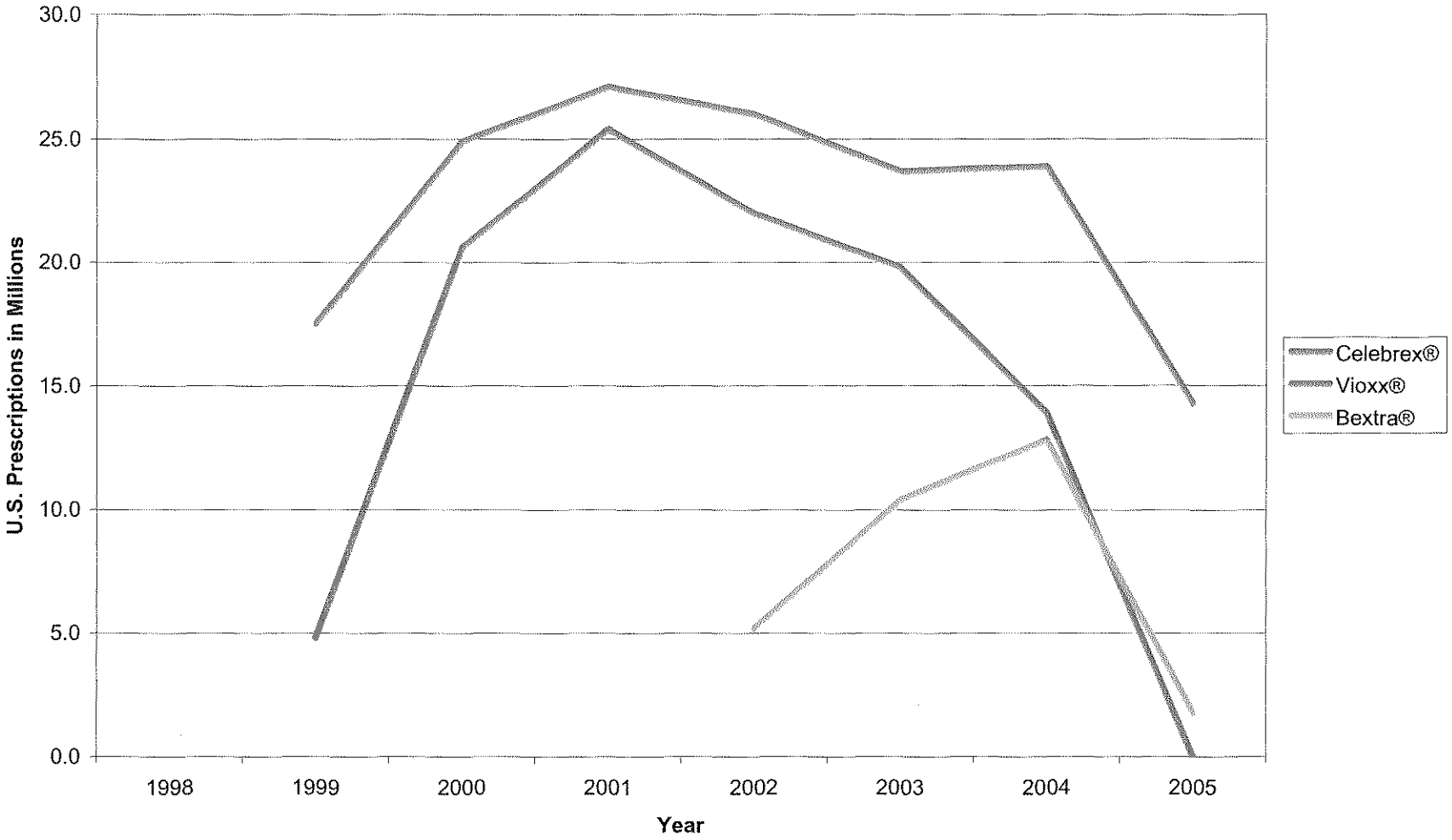

Figure 5: U.S. Sales of NSAIDs Pre and Post Celebrex® Launch

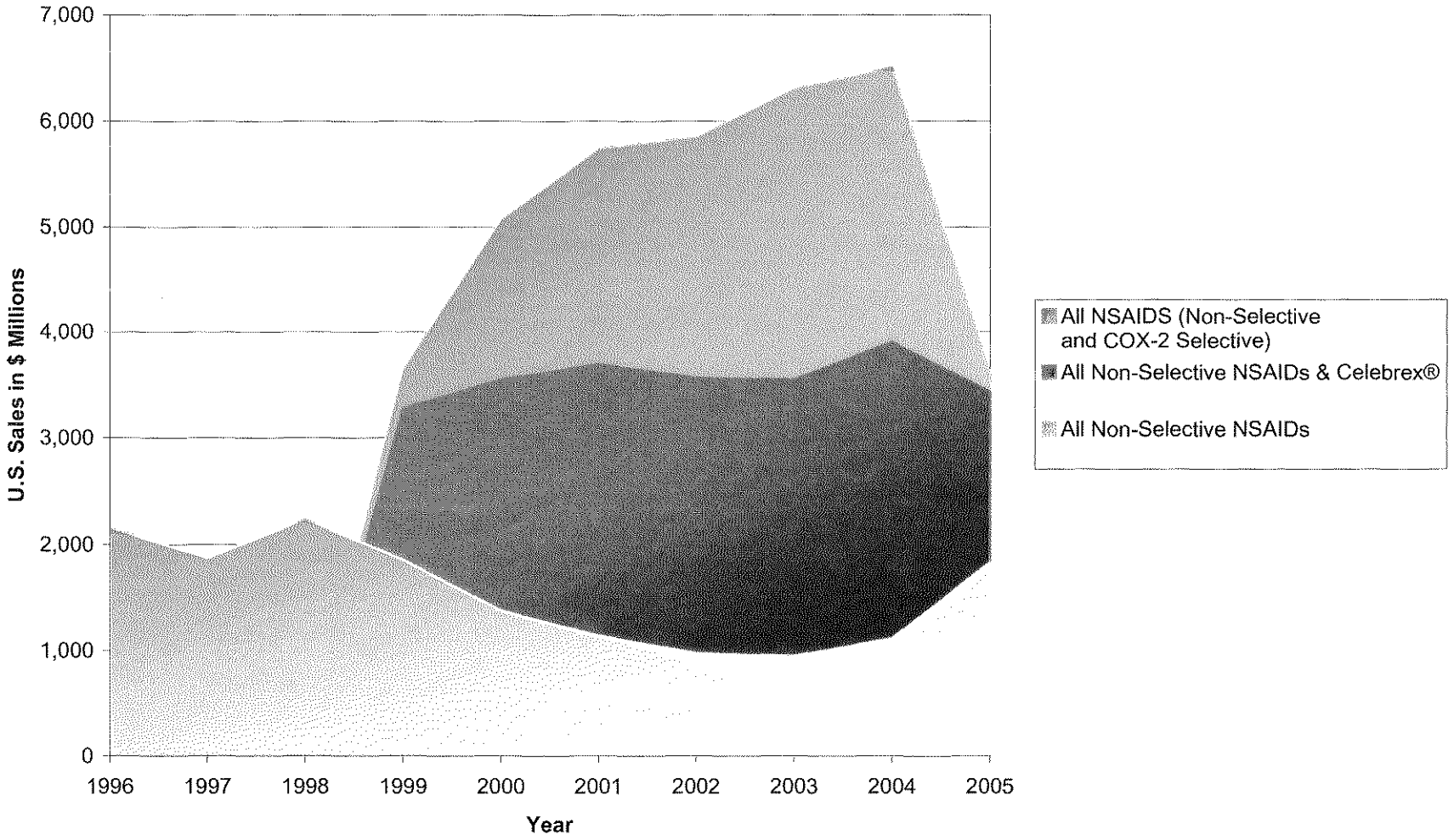

Figure 6: U.S. Prescriptions of NSAIDs Pre and Post Celebrex® Launch

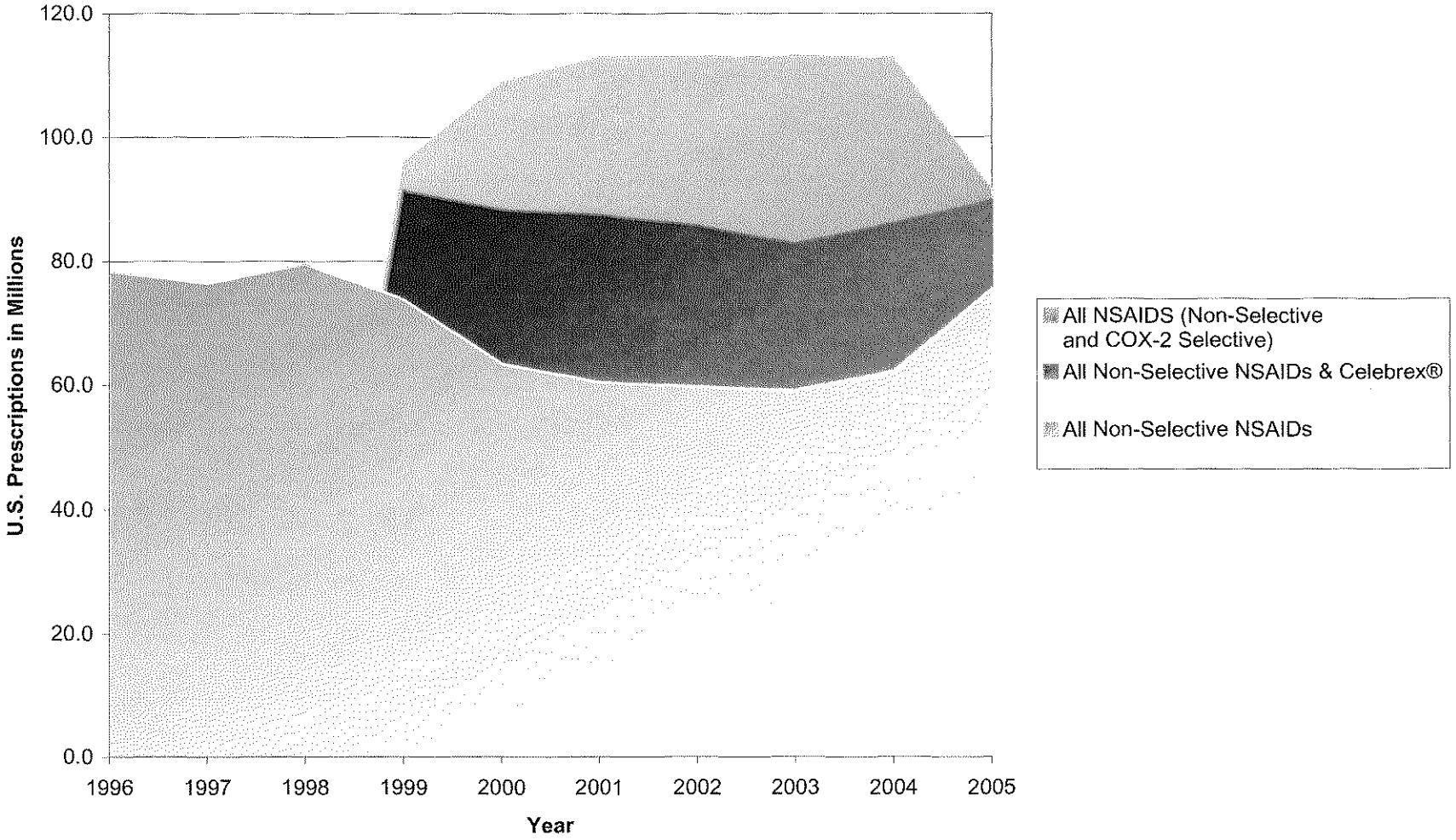

Figure 7: NSAID Market Share from 1999-2005

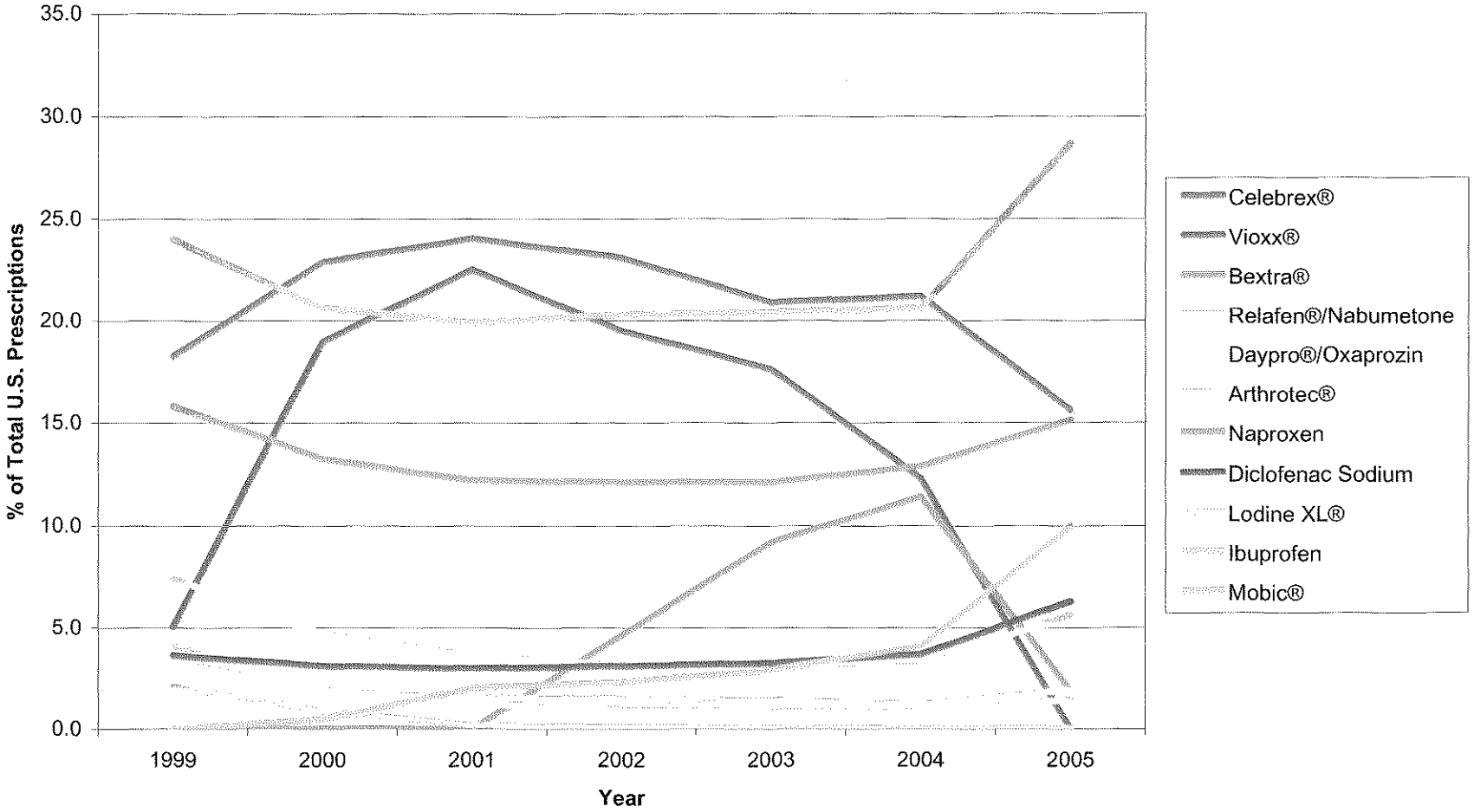

Figure 8: COX-2 Selective NSAID Market Share

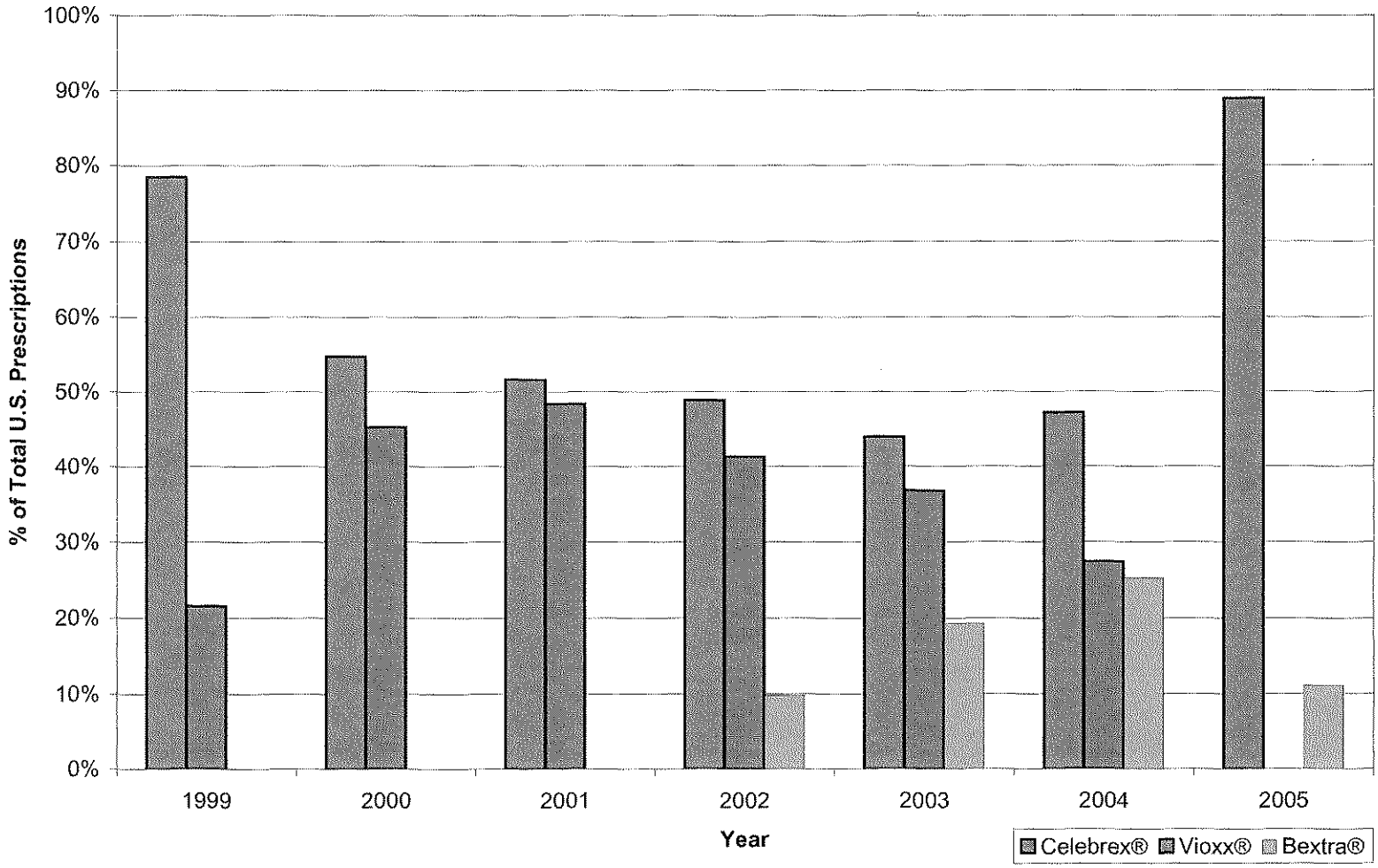

Figure 9: Cumulative Present Value of U.S. Sales Discounted Back to the Year of Launch By Year Through 2005 of Four NSAIDs Launched From 1999-2005